IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

CareToLive,

Plaintiff,

Case No. 2:08 CV 0005

vs.

Judge Frost

The Food and Drug
Administration (FDA),
Commissioner Andrew von Eschenbach

Defendant.

MOTION FOR LEAVE TO CONDUCT/COMPLETE DISCOVERY UNDER CIVIL RULE 56(f)
AND
PARTIAL MEMORANDUM CONTRA TO DEFENDANT FDA'S MOTION FOR SUMMARY JUDGMENT

Now Comes Plaintiff, CareToLive, on behalf of its members and all suffering late stage prostate cancer patients and their families who have now been denied a *proven safe and effective treatment* for over two years and request leave from this Court to conduct a limited amount of discovery so as to more fully respond to the Motion for Summary Judgment filed by Defendant, as further set forth in the attached memorandum.

Respectfully submitted,

S/Kerry M. Donahue

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Kerry M. Donahue (0061105)
BELLINGER & DONAHUE
6295 Emerald Parkway
Dublin, Ohio 43016
Telephone: (614) 761-0402
Facsimile: (614) 789-9866

MEMORANDUM

HISTORY OF FOIA CASE

Previously the Defendant FDA advised this Court that responding to the Plaintiff's FOIA request was "complex" and that there was no urgent or compelling public reason that justified giving the FOIA priority over other important FOIA requests to the agency. See "Defendants Motion to Stay", Doc. # 10, p. 3.

> DIDP assigned it to the "Complex Track" because DIDP determined that Plaintiff's request sought documents not readily available and would require DIDP to search for and possibly redact documents. Sager
> Decl. ¶ 29.

The labeling of this matter as "complex" was a legal and tactical maneuver that was a complete fiction. It was done intentionally to mislead this Court. Plaintiff previously and properly argued that this was *not* a complex matter and suggested that the documents could be easily located on the Computer of Dr. Richard Pazdur, at the main office of the FDA in Rockville, Maryland. The final response indicates clearly that neither the FOIA personnel nor anyone else within the agency, and specifically, within the agency's information technology (IT) office, actually conducted a proper search for the documents.

On May 22, 2008 Defendants successfully obtained a stay of this matter (Doc. #. 23) until December 1, 2008. At that time, this Court indicated that if required, the Court would give the FDA additional time to respond to the FOIA, if additional time was needed and if that request was made by the Defendant, but that in no circumstances would the Court extend the response time beyond 15 months, which date would be May 19th 2009. On December 1, 2009 the Defendant did in fact ask for the maximum response time; until May 19, 2009. The Court granted that request, Doc. # 28. On May 19th the FDA filed an incomplete response. Even more egregious is the fact that the FDA failed to use due diligence to obtain a proper response for Plaintiff, over the course of the last 20 months. In addition the FDA did not use due diligence to maintain public records even though such action was so ordered by this Court.

On March 25, 2008, Plaintiff had requested leave of this Court to conduct limited discovery by allowing submission of 20 requests for admission to the FDA. These requests for admission would be directed to the FDA's Richard Pazdur. This Court denied that request *without prejudice to making the request again at the end of the period of stay*, Doc. # 24. The period of stay has ended. On December 1, 2008 Plaintiff made a second

motion for leave to conduct discovery by submitting 20 interrogatories to Defendant FDA. That motion was denied.

The FDA responded to the FOIA request on the last day of the 15 month period granted to them by this Court. That response was one page and had attached to it a 4 page letter to then Commissioner Andrew von Eschenbach, which had already been received by Plaintiff from the Commissioner in January 2008. In an affidavit filed with this Court, Dr. Richard Pazdur declared that he did in fact have correspondence relative to the CareToLive FOIA request but that it had all been deleted from his computer and otherwise destroyed by him.

The first page of the FOIA response from the FDA (CDER Division) stated that "the following charges may be included in a monthly invoice":

Search $0

Review $0

Reproduction $0.40

Total 0.40.

The "complexity" of the search, the request, the review, and the response is indicative of the amount of resources expended by the FDA to conduct this "complex" review, which took more than 20 months to compile. In disregard of the importance of this matter to late stage prostate cancer patients the

Defendant FDA who ultimately provided no real response had originally requested 6 months more than the 20 months this Court granted them. This Court denied the additional 6 months requested by the FDA. It is suspected that the entire review, and Plaintiff exaggerates only minimally, was to ask Dr. Pazdur if he had any responsive documents to which he said "no" and then they asked him to supply an affidavit to that effect. That was the entire complexity of the response. That the FDA designated the FOIA request "complex" should be considered in hindsight by this Court to be at best a mistake, and at worst, an intentionally misleading sham.

THE RICHARD PAZDUR RESPONSE

In an effort to try to avoid this Court allowing discovery in this case, on this issue, the Defendant FDA had Richard Pazdur file an affidavit with this Court (Exhibit D to Defendant's Motion). That affidavit is evasive as to the amount and content of the correspondence but clearly indicates that the sought after correspondence is admittedly on the computer of Richard Pazdur, just as previously asserted by Plaintiff. That Dr. Pazdur deleted the e-mails does not mean they are not recoverable from his computer. When Dr. Howard Scher and Dr. Maha Hussain communicated with Dr. Jesse Goodman (CBER) and with Dr. Andrew von Eschenbach (Commissioner), there also was e-mail correspondence sent with those letters, now commonly

known as “the Cancer Letters”. There also was additional correspondence related to the letters, sent separately from the letters, to each of those other recipients. Because by all appearances there would have had to have been correspondence between Richard Pazdur and the two AC panelists that he selected and invited to the “Provenge” Advisory Committee meeting of March 29, 2007, who both as it turned out had significant reported and unreported conflicts of interest (COIs) and because it would make sense that there was correspondence from and to him because he was the leader of those who demonstrated opposition to Provenge approval (e.g., he was seen passing notes back and forth to opponent oncologist Maha Hussain during breaks in the AC meeting by witnesses present), he clearly had the correspondence (Richard Pazdur in a later interview suggested that the FDA might have looked stupid if it approved Provenge and then later found out that the ongoing IMPACT trial would show it did not work and thus, the FDA would have been seen to look silly for approving a treatment that did not work.) His concern was for the FDA’s image and not the best interest of the Citizens. Dr. Pazdur does not deny that he had other correspondence by e-mail in his affidavit; he just says whatever he did have has been deleted and shredded. Lacking from the Pazdur affidavit is any reference to communications that accompanied the letters or concerned the letters. This is

an intentional omission to avoid disclosure of the contents of the communications between Dr. Pazdur with Dr. Scher, Dr. Hussain AND Dr. Fleming.

Importantly, immediately after the three Cancer Letters became public, after all were leaked to The Cancer Letter, a monthly newsletter produced in a Washington DC home. (This is the same publication that first reported the FDA leak of the Imclone concerns, a leak that later was determined to come from the same Richard Pazdur). The "cancer letters" almost immediately received worldwide attention and were immediately the subject of controversy. Dr. Pazdur clearly would have known in early April 2007 that these letters existed (one, for example, was written by Howard Scher with the help of Dr. Alison Martin from the National Cancer Institute (NCI); a copy of v3 of the letter was found on her government-owned PC at NCI.) Clearly, this and the other two letters were items of importance and would generate great controversy. Also the FDA recently stated that one of Dr. Pazdur's duties is to coordinate activities among different government agencies and thus he would have or should have known of the FDA/SCHER collaboration with NCI/MARTIN on the letter). Those letters infuriated advocates and sparked a May Demonstration in Washington DC and Chicago as well as a meeting between advocates and Commissioner von

Eschenbach. A May advertisement also was published in the Washington Post, asserting that the FDA was dysfunctional based on their actions relative to the Provenge BLA. The letters also spawned several Websites critical of the FDA actions. Dr. Pazdur's admitted destruction of these documents in the face of this controversy and an increasing advocate groundswell of support against the decision to deny approval to Provenge on May 8, 2007, renders his proclamation of immediate destruction of the letters and the accompanying correspondence and communications regarding those letters, dubious, if not suspicious in the extreme.

Most importantly is the admission by Dr. Pazdur that the correspondence was viewed on his computer prior to him shredding hard copies and deleting computer copies of the communications. *That means that those documents are in fact still retrievable.* If they were on his computer and e-mailed to him, then there may still be a copy on his hard drive that could be retrieved by either an FDA IT expert, or an outside IT expert. If he reviewed them, he could also testify as to their content even if destroyed. The above notwithstanding, the FDA, as is the case with all Federal agencies, uses client/server systems linking individual user PCs to central e-mail servers. By law, Federal agencies must retain copies of all incoming and outgoing e-mail for a period well in excess of several years.

Thus, regardless of what may or may not be on Dr. Pazdur's computers, a complete record of *every* e-mail that went in or out of his government-owned computer still exists within the FDA's e-mail server. The FDA FOIA office had an obligation to this Court to look beyond what Dr. Pazdur may or may not have maintained on his computer or in his files. Once they knew the correspondence was once on the computer, they had an obligation to search the agency's e-mail server and process those e-mails deemed relevant to this case. If that action had properly taken place the request would actually be a "complex" request, search and response, more consistent with the FDA's original claim to this Court. Apparently, to the detriment of Plaintiff, in what we believe is a bold attempt to thwart the will of this Court, the FDA made no attempt to retrieve the documents they must know may still be on the computer. In the alternative, the correspondence may also be recoverable from the Internet service provider (ISP) used by the FDA. The Defendant FDA did not use due diligence to obtain these documents, and it appears by their filings that they merely asked Dr. Pazdur to turn them over, a seemingly non complex task.

The declaration by Dr. Pazdur that he destroyed the correspondence *almost immediately* may have been stated in order to avoid the wrath of this Court, and as indicated above, seems a dubious claim. Even if Dr. Pazdur

destroyed the documents before this Courts order not to destroy documents, made at a status conference on August 29, 2007, then it is not entirely clear if they were destroyed prior to the filing of litigation against the FDA and more particularly against Richard Pazdur. The date of deletion may also be obtained by review of the computer by an internal or external Information Technology (IT) expert. It has always been the fear that Richard Pazdur or someone else at the FDA may have destroyed correspondence on the evening of July 30, 2009, the day the litigation was filed.

The fear that the Plaintiff had, that documents would disappear, was presented to this Court on August 1, 2007 by way of Plaintiff's Motion to Preserve Evidence in Case No. 07-729 (Doc. # 3). That motion was denied by this Court following a status conference on August 29, 2007, but based on the concerns expressed by Plaintiff in the motion, the Court did orally order FDA counsel that was present at that hearing, to instruct the parties (which included Dr. Pazdur) not to destroy any documents related to the case. Counsel agreed to do this.

UPDATED HISTORY OF PROVENGE APPROVAL PROCESS

The importance of the denial of due process to the Provenge BLA is evidenced by the events that have occurred since that denial. The FDA's refusal to admit that mistakes were made in the process and more

importantly their refusal to correct the injustice; continues to harm patients and their families. It remains the position of CareToLive that if the Provenge BLA had just received *proper* due process that it would have been approved by the FDA in May of 2007, to the benefit of more than 60,000 men since that time.

Although the case of CareToLive vs. FDA, Case # 07-729 was dismissed for being unripe in that the FDA had not made a final decision (they merely delayed approval for more than 2 ½ years) the e-mails have continued to come in to CareToLive from late stage prostate cancer patients and their families. Not a single patient has been able to access Provenge to date other than through clinical trials. Not a single bureaucrat at the FDA seems to care.

The final decision by the FDA on Provenge approval is now expected by the end of 2009. The FDA has promised CareToLive an expedited review and response to the new or "amended BLA" for Provenge, expected to be re submitted by Dendreon on or about September 2009.

In mid 2008 the interim results of the IMPACT study, which was the ongoing study begun by Dendreon in 2005, from which the FDA requested the additional evidence of efficacy come from, were made available to the FDA. Both an Independent Data Monitoring Company (IDMC), as well as

Dendreon, took the evidence of increased survival and patient benefit to the FDA and requested that they be allowed to resubmit based on that interim data. They both expected that the FDA would grant the request and allow the unblinding of the trial, submission of the data, and resulting approval of Provenge. The FDA denied the request and told Dendreon to continue the trial to completion, which completion was expected to occur in 2009. On April 14, 2009 Dendreon announced that the final results of IMPACT had been reviewed and that there was clear and unambiguous data that late stage cancer patients without good alternatives were benefiting from Provenge in a statistically significant manner and that the Company had hit the pre designated endpoints of increased survival as set forth in the Special Protocol Assessment (SPA) entered into with the FDA. In other words Provenge undeniably works for a late stage cancer patient population as now shown by a large study: It's safe and has much less side effects than the current standard of care, which is a chemotherapy treatment given by oncologists, for those late stage cancer patients.

Since the release and presentation of the data by Dendreon at the American Urological Association (AUA) meeting in Chicago on April 28, 2009, the FDA decided the CareToLive Citizen Petition. They denied it. They missed the opportunity to get Provenge to the patients sooner, by

simply and easily reconsidering the data which had already been found to be sufficient by the overwhelming majority of the FDA selected Advisory Committee (AC) panel, convened in March 2007.

Presented with the *opportunity* by CareToLive, to legally, and in accordance with Congressional oversight to recognize a now known mistake to delay approval of Provenge, which would have accelerated access to a proven safe and effective treatment that has already satisfied the requirements for safety and efficacy previously set forth by the FDA for approval, and approve it for the immediate benefit of cancer patients, the FDA said "no thanks". The FDA mistakenly believed that to do the right thing would mandate that they admit a mistake was made, which they will not do even with the 20-20 hindsight they now possess. In actuality they did not need to admit mistakes. They merely needed to take the humane action to reconsider, based on what they now know to be to the benefit of mankind. They missed an opportunity to change the public perception that the agency is a cold and uncompassionate bureaucracy. In denying the petition they made the choice to protect themselves from imperfection, over the best interests of the patients. Because of this second poor decision, which compounds the first, many thousands more late stage cancer patients will die without access to Provenge. The FDA had a chance to change the image that

it is a statistically rigid, unyielding, and unresponsive agency, but decided not to redeem itself. Recall that the original BLA was denied because the outdated endpoint TTP was missed by two one thousandths of one percent and the observed survival benefit was not the pre specified end point. Never mind that the agency grants "licenses" that are by their nature revocable at any time. The agency always makes the decision that *they think* is in *their* best interest rather than that which is in the Citizen's best interest.

Despite the clear and convincing additional evidence that Provenge is safe and works for a late stage cancer patient population, who are without alternative treatment options, Provenge still remains unavailable to the patients who desperately need it. CareToLive member and patient Ted Girgus is currently suffering and undergoing chemotherapy treatments and he and the other suffering patients need Provenge now to help them in their battle with Cancer. Many other CareToLive members have died since the FDA decision in 2007.

Even though the world knows that Provenge works and is needed by a desperate patient class, the patients still can't get it because the FDA tries to maintain an image of perfection. Only the FDA sees itself as perfect. In the name of the FDA's unyielding ego, men will continue to needlessly die painful deaths without the benefit of a safe and effective treatment. In the

response to the Petition the FDA stated that CareToLive was not Dendreon and that they don't stand in the shoes of Dendreon. They fail to recognize that a Citizen Petition is just that, a request from the Citizens to take action that humanity compels. The FDA forgets it works for the Citizens.

In that Citizen Petition response, which was issued just days after the Pazdur affidavit in this case, the FDA sets forth that Richard Pazdur did not conspire with others to sabotage Provenge, rather that he was *invited* to be a part of the CBER led AC hearing and decision regarding Provenge (this can of course be more confidently asserted after Dr. Pazdur has declared he has destroyed the documents that would demonstrate otherwise). More importantly, one of the reasons set forth by Richard Pazdur in his affidavit, was that he was not involved in a supervisory role in the Provenge matter, so he did not think that the letters sent to him were significant. That they were not important due to his position in the FDA rings hollow and untrue (Dr. Pazdur has been called the "Cancer Czar" and he along with Janet Woodcock lobbied for their division to have control over approvals of immunotherapies). The Citizen Petition response stated Dr. Pazdur was invited to be involved in the Provenge process but clearly they did not want this to be known publicly at the time of the AC, as they kept that fact hush-hush. It certainly would have sent up alarm bells to have such a statistically

rigid and unyielding oncologist directly involved in the process and many would have objected loudly pre meeting to his involvement. Noteworthy is the fact that the *other "participants" at the AC hearing were introduced,* including the PR people who stood up and were introduced in the room and were recognized to take any follow up questions. The only previous evidence presented to the public that Dr. Pazdur was involved was from witnesses at the meeting that saw him passing notes back and forth from his hand selected panelist, oncologist Maha Hussain, and by a head nod by Maha Hussain to Dr. Pazdur when she said at the AC (transcript p. 183) when she was arguing with CBER's Celia Witten:

> "And if that's the case, in another committee that I'm part of, ODAC, it was clearly made by several FDA representatives that in the - the progression-free survival will be only accepted in lieu of survival if somehow it was proven in that disease entity as being predictive. **And there are some members sitting in the back**; they can confirm if I'm misquoting."

Here is the AC transcript

http://www.fda.gov/ohrms/dockets/ac/07/transcripts/2007-4291T1.pdf

where the following introductions also occurred:

> On page 6, Dr. Mulé gets the meeting going. He introduces Gail Dapolito, the Exec Secretary for CTGT. She is going to go over the COI info but before she does, she introduces Karen Riley and Heidi Rebello for the media. Riley and Rebello are from the FDA Office of Public Affairs. Gail then introduces, in that same paragraph, Celia Witten as the sole spokesperson for the FDA.

> At the bottom of page 12, Dr. Mulé asks people to introduce themselves. He starts with Woo.
>
> Page 13: Woo is followed by Marincola, Scher, Tomford and Guilak.
>
> Page 14: Gunter and then Dranoff. The next three are FDA employees who evaluated the BLA and briefing docs: Zhen, Liu and Wonnacott. Then Witten introduces herself followed by Alexander.
>
> Page 15: Chamberlain, Kwak, Calos, Dubinett and Allen.
>
> Page 16: Chappell, Hussain, Samuels, and Terry.
>
> Page 17: Taylor and then Dapolito and Mulé officially introduce themselves.
>
> Disclaimer: The above are not quotes but indented for ease of reading.

Later the FDA did admit that Dr. Pazdur was involved to the extent he selected the two oncologists that participated in the AC panel. A recent FDA press release indicates that Dr. Pazdur coordinates activities across all FDA product centers and ensures collaboration between FDA and NCI:

> "As part of his duties, Pazdur coordinates oncology activities across all FDA product centers and ensures collaboration among the FDA, the National Cancer Institute at the National Institutes of Health, and both public and private cancer organizations."
> http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm163025.htm

That he played an important role in the process is denied by him to explain why he would destroy documents, yet it is now admitted in the FDA

Petition response that he was very involved in the process. The petition response says:

> In addition, CBER determined that it would benefit from review by prostate cancer experts. Also, at CBER's request, Dr. Pazdur from FDA's Office of Oncology Drug Products (OODP), Center for Drug Evaluation and Research (CDER) participated in the advisory committee meeting. Dr. Pazdur has extensive experience in OODP evaluating other prostate cancer therapies.

The Richard Pazdur affidavit says:

> I recall receiving both hard copies and electronic copies of these letters in April 2007. However, *as these letters related to a specific regulatory application conducted by a different FDA Center (CBER),* did not fall under my direct regulatory supervision, and did not require a response from me, I shredded my hard copies of these letters and deleted any electronic records. Emphasis added.

It is misleading and a spin to say that he did not think the communications important because he was not in a supervisory position. He clearly recognized the importance of his communications with Dr. Scher, Hussain and Fleming with the added background light that these were indeed very controversial letters all written by individuals whom he communicated with and whom he selected to be on the AC panel of experts. In light of the allegations that quickly came to light that his selections to the panel had reported and unreported conflicts of interest, along with his invitation to participate in the decision making process, his so called immediate destruction of these communication does not appear reasonable.

RULE 56F

In accordance with Rule 56(f) the Plaintiff requests the relief set forth below in order to fully obtain and present affidavits to this Court. An affidavit by counsel for CareToLive is attached as below.

FEDERAL RULES OF CIVIL PROCEDURE
TITLE VII. JUDGMENT

USCS Fed Rules Civ Proc R 56

Rule 56. Summary Judgment

> (f) When Affidavits Are Unavailable. If a party opposing the motion shows by affidavit that, for specified reasons, it cannot present facts essential to justify its opposition, the court may:
>
> (1) deny the motion;
> (2) order a continuance to enable affidavits to be obtained, depositions to be taken, or other discovery to be undertaken; or
> (3) issue any other just order.

Plaintiff needs relief or leave of this Court to obtain and present evidence and affidavits that the requested FOIA documents are in fact available from the FDA.

REQUEST FOR RELIEF

Plaintiff, Care to Live, requests the following:

1. Leave to submit 20 requests for admission to Richard Pazdur as previously requested by Plaintiff, and/or,
2. leave to submit 20 interrogatories to Richard Pazdur, and/or,
3. a court order directing an IT expert employed by the FDA to review the computer of Richard Pazdur to see if there is correspondence related to the "Cancer Letters" between Dr, Pazdur and Dr. Husain, Dr. Scher or Dr. Fleming, and/or,
4. an order that an IT expert hired by Plaintiff be allowed to review the hardrive of Dr. Pazdur for any information consistent with the FOIA request, and/or,
5. leave to issue a subpoena or a Court order directed to the internet server used by the FDA to ascertain if the correspondence is recoverable, such server information can be ordered to be presented under seal for purposes of issuing a subpoena to them, and/or
6. an order that an IT expert at the FDA examine the computer and provide an affidavit to the Court regarding the presence of any correspondence related to the Plaintiffs FOIA request and the dates of destruction, and/or,
7. an order that the Plaintiff has leave and time to provide to this Court an opinion affidavit from a Plaintiff hired IT expert that advises this

Court on the likelihood that a review of the hard drive or the internet service records would indicate if correspondence related to Plaintiffs FOIA response might be available on that computer or the date of destruction, and/or

8. any other relief this Court deems appropriate.

AFFIDAVIT BY COUNSEL FOR CARETOLIVE

Now comes Counsel for CareToLive under Federal Rule of Civil Procedure 56(f) and swears under oath and asserts to this Court that CareToLive is unable by affidavit to provide proof to this Court of the existence of the requested FOIA correspondence on the computer of FDA employee Richard Pazdur at this time without the relief and/or discovery requested herein. With any or all of the relief requested in the Rule 56(f) motion the Plaintiff is confident it can show that the FDA FOIA response was not complete.

Sworn to by me this 6th day of June 2009.

s/Kerry M. Donahue

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Kerry M. Donahue

Respectfully submitted,

S/Kerry M. Donahue

Kerry M. Donahue (0061105)
BELLINGER & DONAHUE
6295 Emerald Parkway
Dublin, Ohio 43016
Telephone: (614) 761-0402
Facsimile: (614) 789-9866

CERTIFICATE OF SERVICE

This reply was filed by e-transmission and is understood to be served on all parties by the courts electronic notification system this 6th day of June 2009.

S/Kerry M. Donahue